

"Conflict of Interest" Disclosure in Health Science: Inadequate Information and a Tool for Enforcing Orthodoxy

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ABSTRACT

Disclosure of conflicts of interest (COI) in public health sciences simultaneously fail to accomplish what they are supposed to, while contributing to scientific bias and personal discrimination. COI disclosures should allow reviewers and readers to understand personal and political motives that might give authors incentives to bias their results, and to know what role funders played in a study, but such information is almost never reported. Our reviews and examples show that reviewers and readers are almost always denied information about authors' important COIs when the authors are part of the political orthodoxy. However, despite the general acceptance of unreported major COIs, there is intense pressure to report the far less informative identity (only) of funders. Since this offers little useful information about motives, it is used primarily to identify researchers who are not affiliated with the orthodoxy and thus have sought funding from alternative sources. The funding is then used as a rationale for dismissing the disfavored results without regard to their scientific merit. The peer review process

should assess the merits of analyses and vet them in spite of any COI. Instead, COI disclosure is primarily used to focus on politics-of-identity, thereby becoming a substitute for legitimate scientific analysis.

Keywords: Ethics of publication, conflict of interest, publication bias, peer review

A much-discussed problem with the peer review system is that it very effectively allows the orthodoxy in a field to delay or even prevent the presentation of new innovations or alternative viewpoints. Overcoming this tendency, whether it is due to active attempts to censor particular views or simply the inability of rushed and unenthusiastic reviewers to appreciate analyses that are not immediately familiar to them, is a multifaceted challenge. One particularly pernicious, though often unrecognized, contributor to this problem in the fields of epidemiology and related public health sciences is the "conflict of interest" (COI) or "competing interests" disclosure statement.

WHAT COI STATEMENTS SHOULD DO AND WHAT THEY ACTUALLY DO

Public health sciences, like all science but perhaps more than most, have subjective components and researchers often have worldly preferences that might affect their choices. One tool for recognizing researchers' potential motives, and how they might affect analytic choices, should be COI disclosures. But in health science, as practiced, these arguably do more harm than good.

Often journals only demand financial COIs, and authors almost never provide more, even if the journals do ask for it. But non-financial COIs are nearly ubiquitous, encompassing investigators' pet theories (including defending past writings), worldly goals or preferences (political, religious or quasi-religious), and desire to publish an "important" result. For anyone other than employees of stakeholder organizations, these non-financial COIs are likely to be the most important. After all, it is absurd to think that independent researchers who possess marketable skills would be substantially influenced to depart from their beliefs and preferences by the prospect of getting a grant. If they really made choices based on money they would take better paying jobs, and forgo the modest income and time consuming hassles that come from research grants.

Moreover, the financial COIs that most matter are not reported. Disclosures typically only identify the institution that funded the research and perhaps a cryptic grant program identifier, often not disclosing authors' other relevant financial relationships. More useful information, such as who initiated the study and whether the funder follows a "hands-off" policy, are seldom revealed. Without this information, ambiguity abounds over such issues as: did the funder design the study? (as is often the case with pharmaceuticals); can the funder suppress results? (as is often the case for funding by governments and non-governmental organizations); did the request-for-proposals

pre-specify preferred results? (as is often the case with government funding). Identification of funding sources alone reveals little about what truly influences research design, bias toward particular results and political influences. Being employed by an organization that has official opinions, including government agencies and advocacy groups, creates a clear financial COI. Although, a savvy reader can infer this from the affiliation statement, this type of COI is almost never acknowledged in the disclosure.

Finally, COI disclosure in public health sciences is worse than merely useless, because it is often used to enforce orthodox beliefs. Most public health research and publishing is closely tied to organizations, corporations, or government entities that prefer (or even mandate) particular results. The dominant political faction favors approaches that are non-libertarian, command-and-control, non-welfarist, purity oriented, and anti-corporate (with the exception of corporations that provide pharmaceuticals or other Western medical interventions). Researchers who depart from this can typically be identified by the fact that they cannot get funding from traditional sources, and must seek it elsewhere. COI statements then can be, and are, used to identify research that is not part of the orthodoxy and censor it during the review process or deny the validity of the results if they are published.

The following provides empirical evidence in support of the above analysis.

REVIEW OF LITERATURE

Recent writings on the topic of COI in health science, agree that factors other than funding source usually have more and earlier effect on researchers (e.g., [1-3]). Despite the call for more complete disclosure, our systematic review of COI statements in public health science articles published in 2008 and 2009 finds that such factors are rarely reported. We reviewed 500 randomly selected research articles from 10 leading epidemiology and

public health journals, cataloguing the type of information presented in COI statements. (We will report the full methods and results in a longer publication.) We found that funding organizations are widely, acknowledged (66% of articles). But there was very limited information about the implications of the funding source, such as whether the funder specified the goals, methods, or conclusions (<10% of the articles that mentioned a funding source had any such information). Only 1% of articles mentioned the near-ubiquitous non-financial COIs, such as authors' previous work or organizational affiliations, even though 33% identified the institutional affiliation of at least one author as an organization that may have a political position or other policy relating to the subject matter.

DISCLOSURE OF INFORMATION BEYOND FUNDING SOURCE

A concerted search revealed that COI statements that go beyond limited financial information are vanishingly rare. Two of us (CVP, KH) routinely report our worldly goals that motivate our research, particularly our goal of improving public health by promoting tobacco harm reduction (see snipurl.com/iwhhn and other examples at TobaccoHarmReduction.org). This goal puts us at odds with the orthodoxy that controls almost all available funding, which supports only abstinence and command-and-control approaches to reducing the harms from smoking. But, as we point out, our goals influence us, and thereby determine what funding we seek, not the other way around. Another example of interests that should clearly be disclosed, but are not motivated by funding, appears at the end of this paper.

FAILURE TO DISCLOSE IDENTIFIABLE COIS

Perhaps, it might be argued, only the most honest and scrupulous of authors could be counted on to volunteer otherwise undiscoverable information about their beliefs,

goals, associations, etc., and so bright-line verifiable information (like sources of funding) has to serve as a proxy for motives. But it is not difficult to find examples where even clear verifiable information is not effectively reported.

-The American Cancer Society (ACS) is an organization that engages in both political activism and research. In the case of tobacco, the activism includes calls for aggressive public policy and opposition to harm reduction, and their research results somehow always tend to support these preferences. A PubMed search for "tobacco" and "Thun" (Michael Thun is the ACS officer involved with most such research) finds 21 original research articles published since 2003. A review of those articles reveals that none disclose that one or more authors earn their salaries from an organization that is actively involved in promoting particular relevant public policies. In only one article did Thun disclose anything; that he had worked as a testifying expert witness in "tobacco-related cases".

-One of the most active and aggressive proponents of indoor smoking bans, Stanton Glantz, has been an author of many studies and reviews relevant to such policies, including some of the most extreme, and thus presumably upwardly biased, estimates of the effects of second hand smoke. Glantz has repeatedly attacked researchers who reach other scientific conclusions; often this involves claims of COI. Yet based on a review of his writings, we are aware of no cases where Glantz has identified his public policy goals in a COI disclosure, or even provided a comprehensive picture of his many financial ties to political activist organizations (see snipurl.com/iwfvv and snipurl.com/iwgkx). Glantz is also one of the many researchers who have conducted research on tobacco industry documents funded by a source that basically requires the researchers to reach particular conclusions. In at least one case, Glantz submitted a grant proposal that contained extensive information about the conclusions he intended to reach

(snipurl.com/ix3ta). Neither the requirements of the funder nor the promised conclusions in the research were identified for the obvious conflicts with unbiased science that they are (see [4]).

-Expert witnesses employed by the plaintiff in a product liability lawsuit against a smokeless tobacco manufacturer, Stephen Hecht, Scott Tomar, and Jack Henningfield, have published numerous articles related to the topic over the last two years (including at least one that seems remarkably related to the lawsuit), systematically failing to disclose their COI. They also appear to have generally or always failed to disclose their similar role in previous lawsuits. Yet when one of us pointed out one of these failures to disclose to the journal *Nicotine & Tobacco Research* (an orthodox anti-tobacco activist publication), they not only refused to publish an erratum, but the editor, David Balfour, launched an attack to try to censor the freedom of speech and destroy the research program of the researcher who reported it. Following a disturbingly common practice, Balfour tried to justify ignoring an indisputably accurate analysis (ironically, an analysis of unreported COI) by attacking the author of the analysis as having a COI (see snipurl.com/iwbib for details).

Even for clear COIs like these that are easily identified and confirmed, and thus do not depend on a confession of personal preferences, nothing was reported other than the relatively uninformative identity of the funding organization. Indeed, it appears (though is difficult to verify) that partisans of orthodox political positions in public health consider their COIs to be validations of the research (e.g., that decisions to fund research that has not occurred yet validate its quality), and even points of pride.

DISCLOSURE AS ENFORCEMENT OF ORTHODOXY

The process for determining what research is allowed to happen (e.g., the peer-review

process for assigning grants or providing access to data) is rife with political influence. It is difficult to imagine how to prevent those who control funds, data, and other resources from using them to support their own political goals. In the many subfields of public health science characterized by an "us-versus-them" mentality (drug use, including tobacco and alcohol; industrial pollution; occupational safety; sexual behavior; food marketing; etc.), the political divides are particularly apparent, and it is only the most naïve observers who think that any entity, particularly government agencies, can be genuinely neutral.

Fortunately a plurality of interests (and thus resources) often allows a few researchers to do work that the dominant orthodoxy would not support. Unfortunately, in public health sciences, research that could not get funding from orthodox sources is then easily identified by the disclosure of the identity of the funder (sometimes, but not always, industry stakeholders) and is often censored by the orthodoxy as a result. To put it in somewhat overly-stark terms, political partisans on one side do not even acknowledge their interests, as noted above, while any research associated with partisans on the other side is ignored. The latter results in particular research methods or entire ways of thinking being stricken from the record because, as one of us put it in the title of a recent article [5], "who else would fund such research?"

-The aforementioned article notes that the widely-reported studies that conclude that restaurants and bars never suffer financial losses due to indoor smoking bans, are funded and conducted by proponents of such bans, and consistently use methods that cannot possibly identify whether some merchants lose or gain. However, studies using methods that can identify such information are frequently funded by cigarette companies. These studies are repeatedly ignored in what are claimed to be summaries of the literature by ban proponents; they are sometimes alluded to but then never explicitly listed based on the excuse that they

fail to meet proper COI guidelines. This excuse then allows ban proponents to dismiss disfavored methods and results and so no honest discussion or criticism is ever performed for readers. Claims of COI substitute for honest debate over important public health issues.

-Claims of COI are cited to reject almost every submission to most journals from proponents of tobacco harm reduction (THR). Because the orthodoxy opposes THR, the researchers doing substantive research on the topic have sought and received funding from industry, which is then used as an excuse to ignore all the research. In a particularly blatant case of the concept of COI being used as an unthinking *ad hominem* weapon, papers that could not conceivably have scientific bias are rejected based on allegations of COI. In two recent examples of what has occurred to us dozens of times, papers that two of us wrote were reviewed by Joseph DiFranza (the papers and reviews can be found at snipurl.com/iwfm8 and snipurl.com/ix3dz). The papers explicitly noted that the purpose of the research was to examine factors that could interfere with THR efforts, the methods and data collection instruments were reported in detail, and the data was made available to the reviewers. Thus, it is difficult to imagine any room for the hidden biased analysis that COI disclosures are supposed to help protect against. Indeed, DiFranza offered little substantive analysis of where there might be bias or scientific weakness, but still accused the authors of having COI (alleging it was partially undisclosed) and insisted that the submissions be rejected.

If the actual content of an analysis is assessed during peer review, then funding source or any other factors, including political biases and reputation should offer no further useful information. While it is overly idealized to expect such a complete scientific review that all biased analysis is detected (and in public health sciences such review is often impossible since many authors do not really report their methods and keep their data secret), when full scientific

review is possible, it should dominate the politics-of-identity, rather than the opposite.

-Our experience suggests that most journals intentionally avoid finding even a single reviewer who is among the actual peers of heterodox authors, accepting only reviews from political opponents. When a journal does publish important research that tends to support THR, commentators declare that it was a failure of peer review, effectively admitting that they consider peer review as primarily a tool for enforcing the orthodoxy.

-In at least one important controversial area, what was arguably the highest quality study for many years was censored from the literature. The McFadden and Kuneman study that called into question the conventional wisdom on some of the effects of indoor smoking bans, based on far more data than were the studies that supported the conventional wisdom ultimately had to be published as an online working paper (see: snipurl.com/iwcr8).

CONCLUSION

While results from tobacco and nicotine research may be more politicized than many other topics in public health, similar patterns can be found in other areas where strong beliefs or a lot of money are at stake. As with many politics-of-identity prejudices about bias and motives, there is certainly some useful and possibly legitimate information contained in funding source disclosures. But science should not be treated as talking-head punditry, where there is not enough information for the audience to judge the substance and so political identity offers important information. The scientific peer review process is supposed to vet the validity of analyses and conclusions, *assisted by* (not replaced by) knowledge of *all* biases that serve as warnings of what substantive errors to be vigilant for. Current practice fails to fulfill this on several counts.

DISCLOSURE

The authors freely admit that they chose which of many available examples to report in the text based on who has personally attacked us with allegations of COI. The authors have been attacked (to varying degrees, documented elsewhere) for their supposed COIs, usually by people with major undisclosed COIs, and have suffered due to the failures of peer review described in the text. This creates an obvious incentive to try to improve the understanding of COI and push back against its use as a political tool. The authors have each chosen to not surrender to the "politically correct" orthodoxy in public health, and thus their careers would likely be improved if political control in the field was weakened; calling embarrassing attention to the actions of the political actors tends to support that goal. The authors receive funding from various sources, some of which are considered politically incorrect by the public health research and activist orthodoxy; the latter observation represents the relevant COI, and nothing useful is learned by identifying the specifics since no funder played any role in this analysis.

REFERENCES

- [1] PLoS Medicine Editors, "Making Sense of Non-Financial Competing Interests", **PLoS Medicine**, Vol. 5, No. 9, 2008, pp. e199.
- [2] C.V. Phillips, "Commentary: Lack of Scientific Influences on Epidemiology", **International Journal of Epidemiology**, Vol. 37, No. 1, 2008, pp. 59-64.
- [3] G.D. Smith, "Big Business, Big Science?", **International Journal of Epidemiology**, Vol. 37, No. 1, 2008, pp. 1-3.
- [4] A. Landman, S.A. Glantz, "Tobacco Industry Efforts to Undermine Policy-Relevant Research", **Am.J.Public Health**, Vol. 99, No. 1, 2009, pp. 45-58.
- [5] M.L. Marlow, "Honestly, Who Else Would Fund Such Research? Reflections of a Non-Smoking Scholar", **Econ Journal Watch**, Vol. 5, No. 2, 2008, pp. 240-268.